

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**In re: Procter & Gamble Aerosol
Products Marketing and Sales
Practices Litigation**

This document relates to: ALL CASES

Case No. 2:22-md-3025

Judge Michael H. Watson

Magistrate Judge Chelsey M. Vascura

**PLAINTIFFS' REPLY IN SUPPORT OF
MOTION FOR PRELIMINARY APPROVAL OF CLASS ACTION
SETTLEMENT, CERTIFICATION OF A SETTLEMENT CLASS,
APPROVAL OF THE NOTICE PLAN AND FORMS OF NOTICE AND
SETTING DATES AND PROCEDURES FOR THE FINAL FAIRNESS HEARING**

Plaintiffs Norma Bernsee, Abby Nelson, Shirley Thiele, Lindsey LaBella, Erica Esquivel, Joshua Wallace, Tyler Baker, Brian Stanfield, Eileen Aviles, Shelby Cooper, Tanya Cooper, Jacob Cooper, Patricia Donadio, James Dethrow, Gregory Pickens, Ryan Rinz, Patricia Kelley, Jeremy Wilson, Dante Melendez, Darrel Stewart, Beth Blake, Angela Hernandez, Lynn Balser Mills, Matthew Lopez, Erik Velasques, Frank Ortega, Nancy Martinez, Evan Clarke, Lagregory Bonner, Haley Canaday, Cheri Casolari, Dan Lewis, Berenice Bernier, Chaka Theus and Sondra Trent (collectively “Plaintiffs” or “Settlement Class Representatives”), by and through their undersigned counsel (“Settlement Class Counsel”), submit this reply in further support of their Motion for Preliminary Approval of the Settlement¹ (“Motion” or “Mot.”) (ECF No. 23).

I. INTRODUCTION

The Settlement before the Court is an excellent result for consumers who purchased P&G’s Aerosol Products which contained the known carcinogen benzene.² It provides for access to either cash or vouchers, at an *unlimited cap* for consumers with proofs-of-purchase and with \$8,000,000 set aside for consumers without proofs-of-purchase. Mot. at 11-12. The Settlement also provides robust non-monetary relief, including new recalls, specifications, testing, and inspections to be undertaken by The Procter & Gamble Company (“Defendant” or “P&G”) to ensure consumers can continue to purchase and use aerosol products like the ones at issue here with safety and with confidence. *Id.* at 12-14. These settlement terms meet or exceed those recently endorsed by the U.S. District Court for the Southern District of Florida at the preliminary approval stage in a similar consumer products case involving aerosol and non-aerosol sunscreen products also containing benzene. *See In Re: Johnson & Johnson Aerosol Sunscreen Marketing, Sales Practices and Products Liability Litigation*, Case No. 0:21-md-03015

¹ Capitalized terms are defined in the Settlement Agreement (“Settlement”) dated July 1, 2022, (ECF No. 23-1). Citations, internal quotation marks, and footnotes are omitted.

² “P&G’s Aerosol Products” (“Products”) has the same definition here as it does in the Motion. *See* Motion at 3-4.

(S.D. Fla.) (ECF No. 68). Yet, a single, attorney, Ruben Honik (“Honik”) opposes preliminary approval of the Settlement. *See* ECF No. 26 (“Opposition” or “Opp.”).

Honik’s Opposition fails to identify any element of the Settlement which warrants the Court’s conclusion that the Settlement should not be preliminarily approved and set for a fairness hearing. Instead, Honik lobs unsupported attacks at the Settlement in his campaign to derail the efforts of at least *seventeen* law firms who have worked together diligently and cooperatively to reach this Settlement. These attacks simply do not survive scrutiny.

The Opposition mischaracterizes the Settlement as “hastily-prepared,” claiming that “self-interest prevailed over the Class’s interests,” and wrongly refers to “the vast majority of the remaining plaintiffs” being “unalterably opposed to this end around,” referring to Settlement Class Counsel as “rogue.” Opp. at 2, 9-10. Though Honik describes the thirty-five Settlement Class Representatives as “rogue,” he names not a single individual (other than himself) who actively opposes the Settlement.³ Opp. at 1. Meanwhile, the Settlement has gained the support of the majority of cases filed against P&G – **15 out of 26**.⁴ Mot. at 9. Despite Honik’s gripes, the Settlement was not the product of “rogue” plaintiffs, and there was no collusion here at all. Opp. at 10. Honik’s Opposition should be afforded no weight. *See In re Wendy’s Co. S’holder Derivative Action*, No. 1:16-CV-1153, 2020 WL 13169460, at *8 (S.D. Ohio Jan. 24, 2020) (granting preliminary approval and rejecting opposition of attorney who refused to work with settling plaintiff’s counsel and later took issue with the settlement’s terms). On August 11, 2022, the Sixth Circuit affirmed the District Court’s approval of the Settlement. *In Re: The*

³ Tellingly, while Honik stated to the Court at the May 3 status conference that the Settlement was reached by the “actions of [a] small handful of attorneys” and that “there are, at the least, 16 other cases which not only didn’t participate in the settlement but were, quite candidly, totally in the dark about it,” Honik is the *only* signatory to the Opposition. *See* Oral Tr. of May 3, 2022 Status Conference, p. 8, lines 7-8; p. 9, lines 7-9. For good reason, no other opposition to this Settlement was filed: it is an excellent result for the Class.

⁴ Since the filing of the Settlement Agreement, a plaintiff in at least one more case, *Campbell v. The Procter & Gamble Company*, No. 1:21-cv-774 (S.D. OH. Filed Dec. 14, 2021), has thrown her support behind the Settlement.

Wendy's Company Shareholder Derivative Action, Case No. 21-3975, 2022 U.S. APP. Lexis 22275, (6th Cir., August 11, 2022).

As detailed in the Motion, the Settlement is the product of arm's-length negotiations by well-informed counsel assisted by a leading industry damages expert, Colin Weir, Vice President of Economics and Technology, Inc., and supervised by a well-respected mediator, Robert A. Meyer, Esq. of JAMS. As Mr. Meyer's declaration confirms, the Settlement is fair, reasonable, and adequate, free of any collusion whatsoever and made in the best interests of the Class.⁵ *See* Declaration of Robert A. Meyer, Esq. ("Meyer Dec."), Ex. 1. This Court should grant Preliminary Approval of the Settlement, allow notice to commence, and begin the process of proving meaningful relief to the consumers.

II. BACKGROUND

Honik's Opposition attempts to distort the facts and circumstances surrounding the Settlement to distract the Court from conducting its preliminary analysis. Plaintiffs therefore correct the record by providing the following background information.

First, Honik questions the extent of knowledge of potential benzene contamination P&G had, as evidenced by his excerpts of a letter from Voyant Beauty, LLC to an employee of P&G only two weeks before the first complaints were filed. Opp. at 3. P&G has, of course, addressed this: the Defendant refers to this as a non-specific letter, sent out *en masse*, received not "weeks" (as characterized by Honik), but only fourteen days before the Valisure Citizen Petition was released and

⁵ It is axiomatic in the Sixth Circuit that the Court gives weight to the belief of experienced counsel that a settlement is in the best interests of the class. *Wright v. Premier Courier, Inc.*, No. 2:16-CV-420, 2018 WL 3966253, at *5 (S.D. Ohio Aug. 17, 2018) (Watson, J.) (citing *Williams v. Vukovich*, 720 F.2d 909, 922-23 (6th Cir. 1983)). *See* Decl. of Gary M. Klinger in Support of Motion for Preliminary Approval ("Klinger Dec."), ECF No. 23-2, at ¶ 2 ("Based on my experience as class counsel..."); ¶ 4 ("I and my Co-counsel have extensively investigated Plaintiffs' claims and facts... reviewed and analyzed informal discovery information produced by Defendants; and made a thorough study of the legal principles applicable to the claims asserted").

P&G took action to recall the products. *See* Opp., Ex. 3, at 6. As discussed herein, the Settlement provides compensation to consumers that far exceeds the relief offered by P&G in its recall.

Second, Honik's supposed status as undersigned of the "first-filed" case does not bring him the merit he insists. This was not a unique investigation conducted by Honik. Rather, the Citizen's Petition against P&G that prompted Honik's client and others to file lawsuits against P&G was public knowledge.⁶ When this news broke, numerous class action lawsuits, including Honik's, were filed across the country within days (or weeks) of one another, including the Ohio lawsuits. While it is true that in some situations, a "first-filed" case may be afforded deference,⁷ that is not the case here.⁸ Mot. at 5. Honik had his opportunity to argue for the consolidation and coordination of the cases in the Southern District of Florida, and although he might be disappointed, the JPML decided to transfer the cases to Ohio.

Third, Honik goes on for great length in the Opposition to portray seventeen experienced consumer protection law firms with hundreds of years of combined experience as "desperate" to settle. Opp. at § II(D). But these words do not follow logically from Honik's previous actions. Indeed, Honik was supportive of Richard Wayne, Esq. and Gary M. Klinger, Esq. – two of the undersigned members of Settlement Class Counsel – being named as co-lead counsel in a putative leadership structure, so long as Honik and others were given a place on any proposed Executive Committee.⁹ *See*

⁶ *See* <https://www.valisure.com/valisure-newsroom/fda-citizen-petition-6-benzene-in-body-spray-products> (last accessed July 29, 2022).

⁷ The first-to-file rule applies to transfers under Section 1404, not Section 1407 as is the procedural posture here. *See Abernrombie & Fitch Co. v. Ace Eur. Grp., Ltd.*, No. 2:11-CV-1114, 2012 WL 2995171, at *4 (S.D. Ohio July 23, 2012) (recognizing first-filed rule as one factor in the more general transfer analysis under § 1404(a)). Even so, it is within this Court's discretion to dispense with the first-to-file rule. *Zide Sport Shop of Ohio, Inc. v. Ed Tobergte Assocs., Inc.*, 16 F. App'x 433, 437 (6th Cir. 2001).

⁸ The JPML is not obligated to follow the "first-filed" rule when deciding a Section 1407 transfer motion. *See, e.g., In re: Truvia Nat. Sweetener Mktg. & Sales Pracs. Litig.*, 996 F. Supp. 2d 1377, 1378 (U.S. Jud. Pan. Mult. Lit. 2014) ("We need not weigh in on . . . whether application of the first-to-file rule is appropriate in these actions, however, in order to decide the present [1407] motion before us.").

⁹ Notably, the Non-Settling Plaintiffs were made aware that Settlement negotiations were ongoing with P&G when they agreed that Klinger and Wayne should lead the litigation. Wayne Dec., ¶ 6.

Declaration of Richard Wayne (“Wayne Dec.”), as Ex. 2. The fact that Honik affirmatively supported Klinger and Wayne to lead this case and, by extension, settlement negotiations, demonstrates his trust in Settlement Class Counsel to craft a fair and reasonable settlement, as they have. In reality, Honik—along with every other plaintiff’s counsel involved in the P&G litigation—was invited *on multiple occasions* to work with Settlement Class Counsel to explore settlement of this litigation. The Non-Settling Plaintiffs, including Honik, declined to participate in those global settlement discussions. Importantly, even after the Settlement was reached in principle, the Settling Plaintiffs had communications with Honik about the terms of the settlement and suggested scheduling a call to discuss his questions. *Id.*, ¶ 8. The Settling Plaintiffs even responded to several inquiries from Honik about the Settlement. *Id.*, ¶ 8; *see also* Ex. C to Wayne Dec. However, Honik offered no feedback whatsoever about how he believed the Settlement could be improved, instead choosing to collaterally attack the Settlement via the Opposition with the hopes that he can derail it altogether and take control of the litigation. If Honik was truly concerned about the terms of the Settlement, he would have offered his critiques *before* its terms were finalized. In light of this fact, the settling parties “did not exclude [Honik] from the [] mediation; [Honik] excluded himself. *In re Wendy’s*, 2020 WL 13169460, at *11 (acknowledging attorney opposing settlement rejected settling counsel’s multiple attempts to work cooperatively and therefore excluded himself from the parties’ dealings). This Court is also aware of Honik’s position, as Mr. Klinger explained during the Status Conference: “We’ve made every effort to bring them into the tent to explore resolution and they’ve sort of rebuffed us at every step of the way.” Oral Tr. of May 3, 2022 Status Hearing, p. 10 at lines at 3-5.¹⁰ Honik’s gripes about the

¹⁰ During prospective leadership discussions in which Honik supported the undersigned’s leading role, Settlement Class Counsel “made them aware that, look, we were still continuing on with our settlement negotiations. It’s [Settlement Class Counsel’s] understanding that they were aware we had a mediation to try to resolve the case...” Oral Tr. of May 3, 2022 Status Hearing, p. 9 at lines at 23-25.

Settlement appear to be nothing more than a case of sour grapes, because he feels he was left out of the negotiations, but that was his own doing—not Settling Plaintiffs.

Further, the argument that Settlement Class Counsel is “desperate” is assuaged by mediator Robert Meyer, where he states: “Based on the mediation session, it was apparent to me that both sides possessed strong arguments and that neither side was assured of a victory should the case be litigated through class certification and to final judgment.” Meyer Dec. at ¶ 7.

The Settlement speaks for itself. It was hard-fought, achieved at arms-length, and accomplished through the assistance of an experienced mediator and damages expert. Honik’s Opposition is simply an attempt to delay the class notice program and draw out litigation without *any* guarantee of meaningful relief which this Settlement already provides.

III. ARGUMENT

In this Circuit, “Courts presume the absence of fraud or collusion” in reaching a settlement “unless there is evidence to the contrary.”¹¹ *Karpik v. Huntington Bancshares Inc.*, No. 2:17-CV-1153, 2021 WL 757123, at *4 (S.D. Ohio Feb. 18, 2021) (Watson, J.) (citations omitted). In fact, “[t]he participation of an independent mediator in settlement negotiations virtually [e]nsures that the negotiations were conducted at arm’s length and without collusion between the parties.” *In re Wendy’s*, 2020 WL 13169460, at *7 (citing cases). And at the preliminary approval stage, the Court need only find that the terms of the Settlement fall within the range of possible final approval. *Ostendorf v. Grange Indem. Ins. Co.*, No. 2:19-CV-1147, 2020 WL 5366380, at *2 (S.D. Ohio Sept. 8, 2020) (citing *In re Telectronics Pacing Sys., Inc.*, 137 F. Supp. 2d at 1015). Thus, “[i]t is neither required, nor is it possible for

¹¹ This analysis is typically conducted at the fairness hearing where class members have an opportunity to object to a class settlement. *In re Telectronics Pacing Sys., Inc.*, 137 F. Supp. 2d 985, 1015–16 (S.D. Ohio 2001); *In re Wendy’s*, 2020 WL 13169460, at *6 (rejecting arguments raised by individual who filed opposition to preliminary approval and finding that he was “free to raise any substance-related concerns he has at the settlement hearing”). Honik will have his opportunity to lodge an objection at the appropriate time. But by filing his Opposition now, Honik seeks two bites at the apple. Even if the Court wishes to hear Honik’s arguments now, none of his arguments are persuasive for the reasons stated herein.

a court to determine that the settlement is the fairest possible resolution of the claims of every individual class member; rather, the settlement, taken as a whole, must be fair, adequate and reasonable.” *Sby v. Navistar Int’l Corp.*, No. C-3-92-333, 1993 WL 1318607, at *2 (S.D. Ohio May 27, 1993) (citation omitted).

For the reasons set forth below, the arguments raised in the Opposition are meritless and preliminary approval should be granted so the thousands of Class Members can decide for themselves—not a single, attorney—whether they want to participate in the Settlement.

A. Honik’s Attacks on the MDL Procedure Lose Focus of the Importance of the Settlement.

Honik stresses that the Multidistrict Litigation Act was set-up to prevent a “conflict over control of litigation,” and insinuates that the Judicial Panel on Multidistrict Litigation (“JPML”)¹² and the Court, failed in this task. Opp. at 12-13. Honik’s argument is misguided.

First, “[p]ublic policy generally favors settlement of class action lawsuits.” *Karpik*, 2021 WL 757123, at *6; *see also Wright v. Premier Courier, Inc.*, No. 2:16-cv-420, 2018 WL 3966253, at *3 (S.D. Ohio Aug. 17, 2018) (Watson, J.) (“[m]ost class actions are inherently complex and settlement avoids the costs, delays, and multitude of other problems associated with them”) (citations omitted). In this case, the Settlement confers immediate benefits on the Class Members, avoids the risks and expense of further litigation, and conserves judicial resources.¹³ In evaluating class settlements, a court seeks “whether [a] proposed settlement falls within the range of what a fair negotiation [] would produce.” *In re Wendy’s*, 2020 WL 13169460, at *6. When examining whether a settlement warrants preliminary approval, courts often consider “whether counsel had an adequate appreciation of the merits of the case before negotiating.” *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 537 (3d. Cir. 2004) (quoting

¹² Honik makes an ill-fated attempt to criticize the MDL process. Indeed, the JPML has very broad discretion when deciding a Section 1407 motion. *See* 28 U.S.C. § 1407(e) (grant of transfer is only appealable via petitions of “extraordinary writ”).

¹³ To quote this Court: “Settlement is encouraged.” Oral Tr. of May 3, 2022 Status Hearing, p. 19, lines 8-9.

In re Cendant Corp. Litig., 264 F.3d 201, 235 (3d Cir. 2001) (internal quotation marks omitted)). However, a “preliminary fairness assessment ‘is not to be turned into a trial or rehearsal for trial on the merits,’ for ‘it is the very uncertainty of outcome in litigation and avoidance of wasteful and expensive litigation that induce consensual settlements.” *In re Wendy’s*, 2020 WL 13169460, at *6 (citations omitted).

Settlement Class Representatives and Settlement Class Counsel completed a thorough investigation prior to reaching the Settlement. Meyer Dec. at ¶¶ 4-5. Honik cannot posit any credible argument regarding Settlement Class Counsel’s pre-mediation preparation. Settlement Class Counsel—a deep bench consisting of at least seventeen different law firms—are experienced in class action and consumer product litigation, and the Settlement was reached only after their extensive review of information produced in preparation for mediation, informal discovery, briefing and conversations with a mediator well-versed in consumer class actions. Moreover, in advance of mediation, Settlement Class Counsel hired the highly respected damages expert, Colin Weir, to conduct a condensed conjoint analysis based on the data provided by P&G. Meyer Dec., ¶ 6. Before mediation, P&G provided informal and confirmatory discovery, including sales data during the relevant class period that further allowed Plaintiffs to assess the strengths and weaknesses of their claims, and to efficiently value the claims. Mot. at 7. The Settlement was the result of this research, investigation, and discovery, assisted by the efforts of Robert Meyer during a full day mediation and subsequent negotiations. Meyer Dec., ¶¶ 7-9. Moreover, it was only reached pursuant to a mediator’s proposal after an impasse in the negotiations. *Id.*, ¶¶ 9-11. Thus, preliminary approval is warranted. *Karpik*, 2021 WL 757123, at *4 (Watson, J.) (“Courts consistently approve class action settlements reached through arms-length negotiations after meaningful discovery.”).

The Opposition attempts to distract the Court’s attention away from a fair and reasonable settlement to alleged “structural collusion” that Honik suggests could be remedied by organizing a

plaintiff leadership structure—and presumably scuttling the Settlement in favor of continuing protracted litigation.¹⁴ Opp. at 12. However, it should be noted that up until this point, Honik was ready to take advantage of the benefits the MDL process affords litigants – aligning himself with the Southern District of Florida in much the same way P&G did. *Id.* at 9. Upset about the JPML’s decision to transfer the cases to Ohio, Honik’s Opposition seeks to upend the Settlement which will only deny or, at the very least, delay consumers’ meaningful relief and burden the Court with unnecessary, protracted litigation. Furthermore, there is nothing in the record or the Opposition suggesting that Honik ever approached Defendant about settling, which means that Defendant could not even engage in a “reverse auction atmosphere” where only one offer was on the table. *See* Opp. at 2.¹⁵ Regardless, no reverse auction took place here. Meyer Dec. at ¶ 12.

At the May 3, 2022, Status Conference, the Court justifiably stated it “certainly [doesn’t] want to scuttle a settlement, and [it wants] to encourage the parties that have not been – have not previously participated in discussions with Procter & Gamble, at least not fruitful discussion, that they receive the terms of the proposed settlement from counsel...” Transcript of Hearing Held May 3, 2022 (ECF No. 22), at p. 12, l. 18-22. Honik has since been apprised of all information that P&G provided Settlement Class Counsel prior to and during settlement negotiations. *See* “Email from Richard Wayne, Esq. to Ruben Honik, Esq. Dated June 16, 2022” (Ex. C to Wayne Dec.) (acknowledging that P&G provided the relevant documents to Honik on June 7). Settling Plaintiffs reached out to Honik to have that fruitful discussion about how to improve the Settlement, but Honik declined to engage. There is nothing further to do at this point. This Court is performing its job at preliminary approval, and it should not now “scuttle” the settlement based on the unfounded gripes of a single, upset attorney.

¹⁴ And of course, Honik agreed to a leadership structure that would have tasked Klinger and Wayne to lead settlement negotiations, which is exactly what they did here.

¹⁵ “If the mere existence of multiple potential classes were sufficient to prove collusion, the reverse auction argument would lead to the conclusion that no settlement could ever occur in the circumstances of parallel or multiple class actions.” *Gallucci v. Gonzales*, 603 F. App’x 533, 535 (9th Cir. 2015) (internal citations omitted).

B. Honik's Objections to the Settlement Are Premature.

Aside from his complaints about how the Settlement was reached, Honik also raises a few issues with the substance of the Settlement. These arguments, however, are premature. If Honik has an issue with the Settlement, there is a clear delineated process in the Settlement Agreement for Honik to challenge it: he can—if his client(s) chose to—file an objection in the normal course of the approval process just like every other Settlement Class Member will be afforded an opportunity to do. Since the inception of class actions, the objection mechanism and the final fairness hearing have always been the process by which class members challenge settlements. *See, e.g., In re Inter-Op Hip Prosthesis Liab. Litig.*, 204 R.R.D. 330, 335 (N.D. Ohio 2001) (noting that under the Manual for Complex Litigation “objections to the settlement are normally solicited only at the full, final fairness hearing,” not at the preliminary approval stage); *Also see Nypl v. JP Morgan Chase & Co.*, No. 15 CIV. 9300 (LGS), 2016 WL 3211440, at *3 (S.D.N.Y. June 8, 2016) (“The fundamental requirement of due process is the opportunity to be heard ‘at a meaningful time and in a meaningful manner,’ and Plaintiffs retain the ability to object to the settlement agreements and participate in the final fairness hearing.”) (citations omitted); *see also* Manual for Complex Litigation § 21.634, p. 322 (4th ed. 2004) (describing procedures for fairness hearings). Honik will have his opportunity to object at the fairness hearing.

C. The Settlement Does Not Replace FDA Guidance with a More Lenient Standard.

Honik argues that the Settlement “would gut FDA Guidance” because it requires future testing of the Products by P&G for benzene at 1ppm or more. Opp. at 13. Not only is this argument premature, *see supra* III.B, but it is also unfounded. It is well established that private parties cannot contract to restrict FDA enforcement. *See* 21 U.S.C. § 371. Therefore, the Settlement does not, and could not, preclude the FDA from bringing its own enforcement action if it so chose. Further, the injunctive component is specific to P&G and is not absolute.

Honik next asserts that the proposed Settlement conflicts with FDA's International Conference on Harmonization (ICH) *Q3C Impurities: Residual Solvents guidance* ("ICH Q3C guidance")¹⁶ with respect to the permissible levels of benzene to be used in the Products. Opp. at 13. While acknowledging that the FDA's ICH Q3C guidance is non-binding, the Opposition claims that ICH Q3C guidance "*forbids* manufacturers from using benzene where its use is not unavoidable[.]" *Id.* at 14. When its use is unavoidable, the Opposition says that ICH Q3C guidance limits the use of benzene to no more than 2 ppm. *Id.* at 15. The Opposition then contends that because the use of benzene in the Products is not unavoidable, the 2 ppm exception does not apply. *Id.* Based on this theory, the Opposition claims the proposed Settlement, which requires testing to ensure that no more than 1 ppm of benzene is used in the Products, is "in conflict with—and represents a dilution of—the FDA *Q3C Guidance*." *Id.* "The proposed settlement in effect substitutes a more lenient standard for one proposed in an FDA Guidance document," the Opposition asserts. *Id.*

Plaintiffs' counsel can appreciate Honik's argument that the use of benzene in manufacturing the Products is not unavoidable, because it is the same argument made by undersigned counsel (Aylstock and Richards) over a year ago in their complaint filed in the Neutrogena benzene contamination litigation ("Neutrogena litigation").¹⁷ As in the Neutrogena litigation, however, the problem with this argument is that the FDA has not interpreted ICH Q3C guidance so strictly. In fact, to date, the FDA has not restricted the distribution of any OTC benzene contaminated products whose benzene levels fall below 2 ppm. Thus, there is nothing to suggest that FDA is requiring

¹⁶ FDA Q3C – Tables and List Guidance for Industry, available at <https://www.fda.gov/media/133650/download>, at 5.

¹⁷ Like the present case, the Neutrogena litigation was consolidated by the JPML. It is currently pending in the Southern District of Florida before the Honorable Raag Singhal, where preliminary approval of the class action settlement agreement has been granted. Notably, like the proposed settlement here, the settlement there also sets the testing and distribution limits for benzene at up to 1 ppm.

manufacturers whose products contain benzene impurities to first establish that the use of benzene in their products is not unavoidable.

As noted in its recently published “alert” to drug manufacturers, on June 9, 2022, the FDA instead advises that “manufacturers who identify risks of benzene contamination from drug components or confirm the presence of benzene in a drug product should . . . take steps to use ingredients without benzene, or, if justified, use suppliers that minimize risk of unacceptable benzene impurity levels.”¹⁸ Thus, consistent with the agency’s interpretation of its ICH Q3C guidance, the FDA is taking a “stepwise” approach to benzene contamination and only restricting the distribution of products with benzene levels above 2 ppm:

As FDA evaluates the root cause of benzene contamination in certain drugs, the agency is taking a stepwise approach to address the potential for benzene contamination in marketed drug products by *first identifying products that should be immediately recalled or not released for distribution based on a benzene level in the products above 2 ppm consistent with the considerations described in ICH guidance*. Concurrently, the agency will review any Field Alert Reports from drug manufacturers that identify the presence of benzene, in addition to other available information. This information will help inform further updates to FDA’s approach to limiting benzene levels in drug products, as appropriate.

Id. (emphasis added).

For any other drug products with *benzene impurities above the limit of detection but below 2 ppm* (which would include those products testing up to 1 ppm benzene), the FDA states that manufacturers need only be prepared to share with the agency their test results and the potential source of the benzene to assist with the FDA’s analysis:

¹⁸<https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs#:~:text=FDA%20is%20evaluating%20the%20root,leukemia%20other%20blood%20disorders>.

Finding	Contact Method	Notes
Drug product batches already in distribution with benzene impurities above 2 ppm	Contact appropriate ORA Division Recall Coordinators	Field Alert Reports are required for ANDAs and NDAs with such findings for distributed drug products (21 CFR 314.81(b)(1)). Application holders notified of benzene results from the manufacturer of an API used in their product are required to submit FARs
Active pharmaceutical ingredient lot with benzene above 2 ppm	Contact appropriate ORA Division Recall Coordinators	FDA will advise on appropriate next steps such as notifying any entity that received contaminated API.
Any drug product or active pharmaceutical ingredient with benzene above the limit of detection but below 2 ppm	Contact FDA at CDER-benzene@fda.hhs.gov	The manufacturer should also be prepared to share with FDA the methods used and any available information on the potential source of the benzene to assist with FDA's analysis

Id.

Even assuming the FDA had the authority to do so¹⁹, there is nothing to indicate that the FDA would halt distribution (or request a recall) of any OTC drug product like sunscreen, deodorant or antiperspirant that contains less than 2 ppm benzene, regardless of whether the use of benzene in the product is unavoidable. In fact, consistent with the FDA's pronouncements, a defendant manufacturer could argue, as other manufacturers of benzene contaminated products have done, that the presence of benzene in its products is permitted under ICH Q3C guidance at levels up to 2 PPM. *See, e.g., Bowen v. Energizer Holdings, Inc.*, Central District of California, Case No., 2:21-cv-04356-MWF-AGR, ECF Dkt. 50, at p. 22 (Motion to Dismiss Plaintiffs' First Amended Complaint) (citing ICH Q3C guidance for the proposition that "[t]he FDA allows for trace amounts of benzene up to a concentration of 2 ppm.").

As a result, contrary to the Opposition's argument, by requiring that isobutane raw materials intended for use in P&G's Products be tested for the presence of benzene at 1 ppm, and restricting

¹⁹ *See* Dennis Tosh, Executive Summary, FDA Enforcement Man. ¶ 600 (July 2018 Supplement) ("For most product it regulates the FDA does not have statutory authority to *order* a company to initiate a recall. Rather, the agency has the authority to request a recall.")(emphasis in original); U.S. Gov't Accountability Office, Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Processes 10(2006)("FDA does not have explicit authority to require that drug sponsors take other safety actions[.]").

the use of any such material testing above that, the proposed settlement terms are actually *stricter* than the 2 ppm standard arguably deemed acceptable by the FDA.²⁰

For this reason, in the judgment of undersigned counsel, the 1 ppm standard set forth in the Settlement Agreement provides a significant benefit for consumers—all without the need, cost, and risk of litigation over defenses to such claims. *See JLKX Corp. v. Bobcat Energy Resources, LLC*, 2019 WL 4573710 at *7 (N.D. Ohio Sept. 20, 2019) (“At this stage, a court should not second-guess the settlement terms and should presume that the settlement is fair in light of the extensive negotiating conducted by experienced counsel.”); *In re Inter-Op Hip Prosthesis Liab. Litig.*, 204 F.R.D. 330, 350 (N.D. Ohio 2001) (noting “the Court may not second guess the settlement terms.”).

Another factor weighing against the Opposition’s argument that the 1 ppm standard is illusory is that 1 ppm is the same standard agreed to by the defendant manufacturers in the Neutrogena litigation, and that settlement has been granted preliminary approval. *See Order Granting Motion for Preliminary Approval of Class Action Settlement, In re Johnson & Johnson Aerosol Sunscreen Mktg., Sales Prac. & Prods. Liab. Litig.*, MDL 3015 (Ex. 3). This supports a finding that the injunctive component of the proposed settlement is not illusory. *See Karpik*, 2021 WL 757123, at *8 (Watson, J.) (granting final approval to class action settlement, finding that recovery “is in line with other ERISA 401(k) settlements that have received court approval.”).

Finally, the Opposition’s claim that the 1 ppm standard is illusory because P&G’s contract manufacturer reported it was “able to secure supply of hydrocarbon propellant that has a guarantee from our source(s) of < 1 ppm Benzene” is unconvincing. Opp. At 15. First, obtaining a supply of

²⁰ *See* <https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs#:~:text=FDA%20is%20evaluating%20the%20root,leukemia%20other%20blood%20disorders> (“Drug manufacturers with a risk for benzene contamination should test their drugs accordingly and should not release any drug product batch that contains benzene above 2 ppm, consistent with the recommendations described in ICH Q3C.”); <https://www.fda.gov/drugs/drug-safety-and-availability/frequently-asked-questions-benzene-contamination-drugs> (same).

propellant at less than 1 ppm benzene is consistent with the FDA's recommendation that manufacturers should "use suppliers that minimize risk of unacceptable benzene impurity levels."²¹ More importantly, however, there is little value to the Class in P&G having entered into a private contract before the litigation began when that agreement is unenforceable by Class members and leaves P&G free to return to its old ways. Conversely, courts have consistently found significant value in obtaining an order requiring a defendant manufacturer to implement nonmonetary/injunctive relief measures. This is because the proposed settlement will "make the injunctive relief both binding and enforceable." *In re Wawa, Inc. v. Data Security Litig.*, 2022 WL 1173179, at *9 n.4 (E.D. Pa. April 20, 2022) (rejecting objector's claim that the injunctive relief under the settlement "is illusory if it was in the company's interest to institute the changes anyways because, as is the case here, the Settlement will make the injunctive relief both binding and enforceable"); *Zepeda v. PayPal, Inc.*, 2017 WL 1113293, at *13 (N.D. Cal. Mar. 24, 2017) (rejecting objector's claim that injunctive relief was illusory "because PayPal implemented the changes to its business practices before it was legally required to do so," finding that "the Settlement will make the injunctive relief both binding and enforceable, ensuring that Defendants maintain such practices until two years following the date of the Preliminary Approval Order. In the absence of the Settlement, Defendants would be free to cease providing such relief to its users.")). Thus, contrary to Honik's position, the 1 ppm benzene limit negotiated in the proposed Settlement has provided, and will provide, valuable injunctive relief to the Class.

Lastly, the correct analysis at this stage is not whether the injunctive component "replaces" FDA Guidance (it does not), but whether the injunctive component has an impact on the fairness and adequacy of the Settlement. The class period here runs from 2015 through the end of 2021 and the injunctive relief will not begin until after the Settlement's execution. Thus, if class members later feel

²¹ <https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs#:~:text=FDA%20is%20evaluating%20the%20root,leukemia%20other%20blood%20disorders>

that the injunctive relief was not sufficient, they will not be barred from bringing future claims for products purchased after the end of the class period. Additionally, if class members believe they have suffered physical harm resulting from the use of the Products, they are not barred from pursuing such a claim against P&G because the Settlement does not release any claims for personal injury.

D. The Settlement Provides a Greater Value for Class Members Than the Recall Program Did.

Honik argues that the Settlement is inadequate under Rule 23(e)(2) because, according to the Opposition, P&G's unilateral recovery program was already in existence and because recovery under the Settlement is allegedly less than what is received under the voluntary recall. Opp. at 15. Not so.

The P&G recall is over. Despite Honik's contention that "[u]nder the recall program, there was no cut-off date for past purchases," (Opp. at 17) the truth is that a consumer can no longer take advantage of the recall program and it no longer provides any benefit to consumers whatsoever. Further, Honik takes issue with many of the details of the Settlement, including the use of the household as the claim unit, the limitations on recovery for those without proof-of-purchase, and other considerations. Opp. at 16-17.

The Settlement does not put Class Members in a worse position. There are stark differences between the voluntary recall program and the Settlement which show that the Settlement provides significant benefits to consumers. *See* Ex. C to Wayne Declaration and Ex. 4.

Honik suggests the Settlement Agreement's terms could be better. *See* Opp. at 15-17. However, it is not the Court's job, at this juncture, to engage in such speculation.²² *In re Wendy's*, 2020

²² Moreover, the settling parties negotiated attorney's fees after they reached a material agreement as to all substantive terms of Class relief, which supports the fairness of the Settlement. Klinger Dec. at ¶ 13; *see also Gascho v. Glob. Fitness Holdings, LLC*, No. 2:11-CV-436, 2014 WL 1350509, at *25 (S.D. Ohio Apr. 4, 2014) ("The risk of collusion is also lessened in this action because the parties negotiated the payment of attorney[] fees and costs after having reached agreement on the relief to the Class and Subclasses."), report and recommendation adopted, No. 2:11-CV-436, 2014 WL 3543819 (S.D. Ohio July 16, 2014), *aff'd*, 822 F.3d 269 (6th Cir. 2016).

WL 13169460, at *6 (*citing City of Plantation Police Officers' Employees' Ret. Sys. v. Jeffries*, 2:14-cv-1380, 2014 WL 12780342 at *3 (S.D. Ohio Sept. 26, 2014) (stating that a “proposed settlement is not to be judged against a hypothetical or speculative measure of what might have been achieved by the negotiators”). Moreover, the Settlement meets or exceeds the terms recently approved in a near-identical case. *See In Re: Johnson & Johnson Aerosol Sunscreen Marketing, Sales Practices and Products Liability Litigation*, Case No. 0:21-md-03015, ECF No. 77 (S.D. Fla.) (where the District Court preliminarily approved a settlement involving sunscreen products allegedly contaminated with benzene for an estimated \$4.85 million).

E. The Scope of the Parties' Agreed-Upon Release is Proper.

Next, Honik argues that the release is overbroad. Opp. at 17-19. Honik misstates the law and mischaracterizes the release.

The Sixth Circuit has held that the question of whether a release is overbroad “is not whether the definition of the claim in the complaint and the definition of the claim in the release *overlap perfectly*; it is whether the released claims share a ‘factual predicate’ with the claims pled in the complaint.” *Does 1-2 v. Deja Vu Servs., Inc.*, 925 F.3d 886, 900 (6th Cir. 2019) (quoting *Moulton v. U.S. Steel Corp.*, 581 F.3d 344, 349 (6th Cir. 2009) (emphasis added)); *see also Franklin v. Midland Funding, LLC*, No. 3:10 CV 91, 2011 WL 3557033, at *13 (N.D. Ohio Aug. 12, 2011) (citations omitted) (“The Release does not state that its application is bounded by the “identical factual predicate” doctrine, but the addition of language releasing claims “arising from the same facts,” or similar formulations, would be unnecessary and redundant. It is, after all, a given that the Release will only be applied insofar as its application conforms to the law.”).

The claims released in the Settlement Agreement share that factual predicate because the release sufficiently limits the categories of relinquished claims to those “arising out of” or “relating to” the pleadings and claims asserted in the Settlement Agreement. § 1.36. To assuage any doubt that the released claims share the factual predicate, the Settlement Agreement clearly states that the released

claims “do not include Claims for personal injury.” *Id.* Therefore, the Opposition’s argument that the release covers claims “based on conduct that is not alleged in the underlying actions” lacks merit. Opp. at 18.

The Settlement here differs greatly from the rejected settlement in *Chavez v. PVH Corp.*, No. 13-1797, 2015 U.S. Dist. LEXIS 17511 (N.D. Cal. Feb. 11, 2015) – a wage and hour case where released claims related to the payment of wages or reimbursement of wages. *Id.* at *15. Opp. at 18-19. As to false advertising class actions (like here), in *Rosado-Acha v. Red Bull GmbH*, for example, the court approved a class action settlement release that released all labeling claims relating to the products at issue. 2016 WL 3636672, at *17-18 (S.D.N.Y. Jun. 29, 2016). The approved release language stated that class members were releasing:

[A]ny and all . . . causes of action of any kind or nature whatsoever . . . whether . . . known or unknown, foreseen or unforeseen, developed or undeveloped . . . or any claim that Plaintiffs or Settlement Class Members ever had, now have, may have, or hereafter can, shall or may ever have against the Released Persons . . . ***arising from or in any way whatsoever relating to the consumption, actions or omissions in manufacturing, advertising, marketing, labeling, packaging, promotion, sale and distribution of the Products***, and/or any claims or omissions regarding any purported benefits, superiority, safety or qualities of the Products or their ingredients, or consumers’ experiences relating to the consumption of the Products . . . ***including those which have been asserted or which could reasonably have been asserted by the Class against the Defendants***

Id. at *18 (emphasis added); accord *Krommenboeck v. Post Foods, LLC*, No. 3:16-cv-04958-WHO (N.D. Cal.), ECF No. 286-1 at 14, 2021 WL 2910205 (N.D. Cal. June 25, 2021) (approving settlement in false advertising action where release encompassed “any and all of Class Members’ causes of action . . . whether past, present, or future, known or unknown, asserted or unasserted, that arise out of or relate to the facts alleged or the claims asserted . . . including without limitation the labeling, marketing, advertising, promotion, or distribution of the Class Products at any time during the Class Period.”). Accordingly, Honik’s attempt to conjure up a concern for an overbroad release should be rejected.

E. All Eligible Claimants Will Receive Funds Under the Settlement, the Recall Program, or a Combination of Both in an Equitable Manner.

Honik alleges the release is overbroad because it bars certain Settlement Class Members from monetary compensation while still subjecting them to the release. Opp. at 19-20. Honik mischaracterizes or misunderstands the actual terms of the Settlement Agreement.

First, Settlement Class Members with Proofs-of-Purchase can make an *unlimited* number of submissions. *See* Mot. at 11. So, no Settlement Class Members are barred from monetary compensation if they have proof of purchase. Secondly, the Settlement encourages participation at a higher rate than was contemplated under the voluntary recall program (which paid out vouchers totaling \$3.6 million and only \$25,000 in cash). Conversely, here, the Settlement provides an *unlimited* value for Class Members with Proof-of-Purchase and sets aside \$8,000,000 for Class Members without Proof-of-Purchase. Mot. at 10. Meaning, the amount available to Class Members without Proofs-of-Purchase exceeds the value paid out *entirely* under the unilateral Recall Program. *Id.*; *see also* Opp. at 6. Additionally, even individuals who submitted three claims without proofs-of-purchase under the Recall Program can still receive compensation under the Settlement – something Honik himself acknowledges. Opp. at 20, n.22. Accordingly, even Settlement Class Members without proofs-of-purchase who exhausted their remedies under the Recall Program can still make a claim for compensation under the Settlement. Honik is simply wrong when he claims that certain Settlement Class Members are barred from monetary compensation while still subjecting them to the release.

F. The Release Does Not Divest FDA Enforcement.

Lastly, Honik claims the release is “inappropriate” because it precludes the FDA from bringing an enforcement action against P&G for the benzene products. Opp. at 20. This proposition is not

grounded in case law or other authority and is patently false. It is abundantly clear that private parties cannot contract to restrict FDA enforcement.²³

IV. CONCLUSION

Honik's self-serving attacks on the Settlement simply do not pass muster. Negotiated by experienced counsel with the assistance of an experienced mediator and advised by a well-qualified industry damages expert, the Settlement is fair, reasonable, and adequate. Plaintiffs respectfully request that the Court grant the Motion in its entirety.

Dated: August 12, 2022

Respectfully submitted,

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²³ See 21 U.S.C. § 371.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the foregoing document was served via the Court's CM/ECF system on August 12, 2022, and has thus been served automatically on all counsel of record that have entered an appearance in Case No. 2:22-md-3025.

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